DETAILED ACTION

Information Disclosure Statement

1. Note that, since applicant has not filed some references in the information disclosure statement filed on April 1, 2009, these references in the 1449 form filed on April 1, 2009 cannot be considered and have been struck-through. Applicant is advised to file non-patent literatures in the 1449 form based on alphabet order in near future so that the examiner can easily review literatures.

Reasons for Allowance

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Kevin Noonan (Reg. No. 35,303) on November 18, 2009.

3. The application has been amended as follows:

In the specification:

Replace the first paragraph of page 1 with--- This application claims priority for PCT/US97/03479, filed on March 14, 1997, now WO 97/35589, and is a continuation of U.S. Serial No. 09/965,515, filed on September 29, 2001, now U.S. Patent No. 6,759,217 B1, which is a continuation-in-part of U.S. Serial No. 09/155,152, filed on Sep. 22, 1998, now U.S. Pat. No. 6,329,171 B1, the entire disclosure of [each of which] U.S. Serial No. 09/155,152 is hereby incorporated by reference.

In the claims:

33. (Currently amended) A method for detecting [a] heterogeneous nuclear ribonucleoprotein A2/B1 RNA in blood plasma from a human, the method comprising the steps of:

a) centrifuging blood from a human [to obtain] and obtaining blood plasma;

b) extracting extracellular total RNA from said blood plasma from said human and obtaining the extracellular total RNA;

c) amplifying a fraction of the [extracted] extracellular total RNA or cDNA prepared therefrom, either qualitatively or quantitatively, using primers [or probes] specific for [a] heterogeneous nuclear ribonucleoprotein A2/B1 RNA, or cDNA therefrom, [to produce] and producing an amplified product; and

d) assaying either quantitatively or qualitatively the amplified product to detect heterogeneous ribonucleoprotein A2/B1 RNA[, or cDNA therefrom] in the blood plasma.

34. (Currently amended) A method for detecting [a] heterogeneous nuclear ribonucleoprotein A2/B1 RNA in blood serum from a human, the method comprising the steps of:

a) extracting extracellular total RNA from blood serum [from] of a human and obtaining the extracellular total RNA;

b) amplifying a fraction of the [extracted] extracellular total RNA or cDNA prepared therefrom, either qualitatively or quantitatively, using primers [or probes] specific for [a] heterogeneous nuclear ribonucleoprotein A2/B1RNA, or cDNA therefrom, [to produce] and producing an amplified product; and

c) assaying either quantitatively or qualitatively the amplified product to detect heterogeneous ribonucleoprotein A2/B1 RNA[, or cDNA therefrom] in the blood serum.

35. (Currently amended) A method for detecting [a] heterogeneous nuclear ribonucleoprotein A2/B1 RNA in pleural fluid from a human, the method comprising the steps of:

a) extracting extracellular total RNA from pleural fluid from a human and obtaining the extracellular total RNA;

b) amplifying a fraction of the [extracted] extracellular total RNA or cDNA prepared therefrom, either qualitatively or quantitatively, using primers [or probes] specific for [a] heterogeneous nuclear ribonucleoprotein A2/B1RNA, or cDNA therefrom, [to produce] and producing an amplified product; and

c) assaying either quantitatively or qualitatively the amplified product [or amplified signal of said] to detect heterogeneous ribonucleoprotein A2/B1 RNA[, or cDNA therefrom] in the pleural fluid.

4. The following is an examiner's statement of reasons for allowance:

Claims 33-35 are allowable in light of applicant's amendments filed on September 9, 2009, the terminal disclaimer filed on March 15, 2007, and the examiner's amendments. The rejections under 35 U.S.C. 112, first and second paragraphs have been withdrawn in view of applicant's amendments filed on September 9, 2009 and the examiner's amendments. No prior art in the record teaches detecting heterogeneous nuclear ribonucleoprotein A2/B1 RNA in blood plasma or blood serum or pleural fluid from a human. No prior art in the record teaches or suggests a method for detecting heterogeneous nuclear ribonucleoprotein A2/B1 RNA in blood plasma from a human, a method for detecting heterogeneous nuclear ribonucleoprotein A2/B1 RNA in blood serum from a human, and a method for detecting heterogeneous nuclear ribonucleoprotein A2/B1 RNA in pleural fluid from a human which comprise all limitations recited in claims 33-35.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance".

5. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen, can be reached on (571)272-0731.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Frank W Lu /
Primary Examiner, Art Unit 1634
November 19, 2009